

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: E. I. DU PONT DE
NEMOURS AND COMPANY C-8
PERSONAL INJURY LITIGATION

CASE NO. 2:13-md-2433

JUDGE EDMUND A. SARGUS, JR.

MAGISTRATE JUDGE ELIZABETH P.
DEAVERS

This document relates to: *Angela Swartz and Teddy Swartz v. E. I. du Pont de Nemours and Company, Case No. 2:18-cv-00136.*

**DUPONT’S MOTION TO EXCLUDE THE SPECIFIC CAUSATION TESTIMONY OF
DR. VITALY MARGULIS**

Defendant E. I. du Pont de Nemours and Company (“DuPont”) respectfully requests that the Court preclude Plaintiff Angela Swartz (“Plaintiff”) from introducing at trial the unreliable testimony of Dr. Vitaly Margulis regarding specific causation. Dr. Margulis’s specific causation opinions are fundamentally flawed because they are based on an unreliable, results-driven methodology that was not reliably applied. As a result, Dr. Margulis’s specific causation opinions do not satisfy the requirements for expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and its progeny. DuPont respectfully requests that this Court exercise its gatekeeping function to strike these opinions and preclude Dr. Margulis from testifying about specific causation at trial.¹

¹ The Court previously ruled on Dr. Margulis’s specific causation testimony in *Bartlett*. See EMO 1. However, DuPont presents additional arguments in support of excluding his different testimony in this case. Among other things, Dr. Margulis’s opinions in this case are based on new improper theories not advanced in *Bartlett*, including a “no safe dose” theory (his opinions would be the same even if Mrs. Swartz had only been exposed to one molecule of C-8), and an unscientific subjective belief that the same criteria that he uses to summarily rule out all other risk factors for Mrs. Swartz’s cancer does not apply to C-8. He also did not follow the professional practices that he uses outside the courtroom.

Dr. Margulis reached his opinions in this case by employing a results-driven methodology based on an improper presumption of specific causation, as evidenced by Dr. Margulis's concession at his deposition that his primary specific causation opinion in this case would have been the same if Plaintiff "had only been exposed to one molecule of C-8." Tr. of June 13, 2019 Deposition of Vitaly Margulis, M.D. (Margulis Depo.) at 27:3-7 (Ex. A).² Dr. Margulis's opinions fall far short of satisfying Federal Rule 702 and *Daubert* and its progeny for at least the following independent reasons.

First, contrary to DuPont's fully preserved, unlimited right to challenge specific causation in the *Leach* Agreement, Dr. Margulis improperly started with a presumption of specific causation based solely on: (1) the Science Panel's Probable Link report on kidney cancer; and (2) another expert's opinion (Dr. MacIntosh) regarding *Leach* class membership.

Second, Dr. Margulis based his primary specific causation opinion on the fiction that the Science Panel made a scientific determination of causation for C-8. Dr. Margulis compounded this fundamental error by subjectively and unreliably employing two different methodologies: one for C-8, and a different one for summarily dismissing all alternative explanations for Plaintiff's kidney cancer.

Third, Dr. Margulis adopted the "no safe dose" theory, which has been resoundingly rejected as an unreliable basis for specific causation expert testimony. Further, Dr. Margulis took no account of what Mrs. Swartz's actual specific amount of increased risk was from her specific individual level of exposure to C-8, and failed to weigh the amount of increased risk from her exposure to C-8 as compared to the amount of her substantially greater increased risk of developing

² DuPont incorporates here by reference the separately filed Motion for Interpretation of the Leach Agreement With Respect to Specific Causation In the Swartz Case, And Motion to Exclude Mischaracterizations Related to the Science Panel in the Probable Link Findings From the Swartz Trial.

kidney cancer from her decades of obesity and decades of high blood pressure, among other alternative risk factors for her kidney cancer.

Fourth, Dr. Margulis did not follow the professional practices that he uses outside the courtroom.

Because Dr. Margulis's opinions suffer from these numerous fundamental errors, DuPont respectfully requests that this Court exercise its gatekeeping function to exclude Dr. Margulis's opinions on specific causation.

RELEVANT BACKGROUND

Plaintiff alleges that her small kidney tumor that was removed in early 2017 resulted from exposure to C-8 in drinking water from (1) a private well at her residential property in Letart, West Virginia during the years 1979-86, despite the fact that *she has no evidence that the water in that well contained C-8 at any time*; (2) a drinking fountain at a Big Ben Food Land store, which received water from the Village of Pomeroy and where she worked as a cashier and clerk on a part-time basis for parts of seventeen months in the early 1990s; (3) transient visits to her Mother's apartment, also served by the Village of Pomeroy between 1990 and 1992; and (4) transient visits to her sister's mobile home, which is served by the Tappers Plains-Chester Water District starting in 1988. *See* Second Am. Pltf. Fact Sheet ("PFS") for Angela Swartz (April 12, 2019) (Ex. B) ("Swartz PFS") at § 26;³ Tr. of Apr. 12, 2019 Depo. of Angela Renee Casto Swartz (Ex. C) ("Swartz Depo.") at 282:10-18 (testifying that the private well was never tested, and she does not know whether or how much C-8 was in the well); 270:17-22, 271:10-272:9 (testifying that she would "get a glass of her tea" or Kool-Aid when she visited her mother, and occasionally a meal

³ Plaintiff's Second Amended PFS has been filed under seal.

such as beans, pork, or meatloaf); 279:5-18 (testifying that she would drink “[o]ne drink” when she visited her sister).

LEGAL STANDARD

I. Plaintiff Bears the Burden of Demonstrating That Dr. Margulis’s Opinions are Admissible.

The burden is on Plaintiff to demonstrate by a preponderance of proof that the opinions of Dr. Margulis are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Plaintiff can only meet this burden by “objective, independent validation of the expert’s methodology; the expert’s bald assurance of validity is not enough.” *Smelser v. Norfolk S. Ry.*, 105 F.3d 299, 303 (6th Cir. 1997).

Because expert testimony “can be both powerful and quite misleading,” district courts must act as gatekeepers to ensure that expert testimony “is not only relevant, but reliable.” *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589, 592 (U.S. 1993); *Thomas v. Novartis Pharms. Corp.*, 443 Fed. Appx. 58, 60 (6th Cir. 2011) (“Under *Daubert* and its progeny, district courts must exercise a gatekeeping role in screening the reliability of expert testimony to keep ‘junk science’ away from juries.”). Federal Rule of Evidence 702 embodies this *Daubert* principle by only permitting an expert witness to offer opinions that are “reliable”—meaning based on sound scientific reasoning and methodology. *See* Fed. R. Evid. 702. If an expert does not employ sound scientific reasoning and methodology, the expert’s testimony is mere *ipse dixit* and inadmissible. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

To determine whether expert testimony is reliable, the court must “make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (U.S. 1999); *see also Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (“[A] Court’s

duty under *Daubert* is to weed out courtroom science from real science.”). To meet this burden, the expert’s opinions must reflect “scientific knowledge . . . derived by the scientific method,” representing “good science.” *See Daubert*, 509 U.S. at 590, 593.

District courts have flexibility to consider numerous factors in determining whether an expert’s opinions reflect “good science,” including “whether an expert developed his opinions for the purposes of testifying.” *Adams v. Cooper Indus.*, 2007 U.S. Dist. LEXIS 55131, at *16 (E.D. Ky. July 30, 2007); *see also Kolesar v. United Agri Prods.*, 412 F. Supp. 2d 686, 697 (W.D. Mich. 2006) (rejecting opinion of expert witness because “her hypothesis [had] all the appearances of a conclusion made for convenience (to support a pre-existing notion) rather than one supported by scientific fact”).

ARGUMENT

I. Dr. Margulis Improperly Assumed Specific Causation for Plaintiff.

It is undisputed that nothing about the Science Panel’s findings established specific causation for Mrs. Swartz.⁴ To the contrary, it is undisputed that the Class Members expressly agreed that DuPont’s ability to contest specific causation was fully preserved. Despite these facts, and instead of conducting any independent scientific or medical analysis, Dr. Margulis started and finished his purported differential analysis with a false presumption of specific causation from exposure to C-8. Dr. Margulis presumed that the Science Panel determined that Mrs. Swartz was at some unknown increased risk of kidney cancer from exposure to C-8, and summarily excluded all other risk factors for kidney cancer from his differential analysis:

Q. Based on Dr. MacIntosh, you assumed she was a Class Member, you also assumed that she was at an increased risk for kidney cancer?

⁴ The fact that the Science Panel did not address or determine the issue of specific causation for Mrs. Swartz is discussed more fully in DuPont’s contemporaneously filed Motion For Interpretation Of The *Leach* Agreement With Respect To Specific Causation In The *Swartz* Case, which has been incorporated by reference.

A. Based on his report, yes.

Q. And, sir, the way that you did [] your differential analysis, it didn't matter to you how low the amount of her increased risk was since you didn't include anything else in your differential. It had to be C-8 that caused her kidney cancer, right?

A. Correct.

Margulis Depo. at 27:18-28:4.

Dr. Margulis ignores that a *specific* causation expert cannot simply rely on a finding of *general* causation (or an agreement not to contest general causation) to establish *specific* causation in an individual. Indeed, courts exclude specific causation experts when their opinions “rest primarily” on methodologies “which relate to general causation.” *See, Lipitor (Atorvastatin Calcium) Mktg. v. Pfizer, Inc.*, 892 F.3d 624, 643 (4th Cir. 2018); *see also Milward v. Acuity Specialty Prods. Grp.*, 969 F. Supp. 2d 101, 108-09 (D. Mass. 2013). As one court has recognized, “[a]n expert . . . cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development. ‘The fact that exposure to [a substance] may be a risk factor for [a disease] does not make it an actual cause simply because [the disease] developed.’” *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1255 (11th Cir. 2010).

Assuming a conclusion—as Dr. Margulis did here—is *not* a reliable methodology for assessing specific causation. For this reason alone, Dr. Margulis should be precluded from testifying on specific causation at trial.

II. Dr. Margulis’s Opinions Are Unreliable Because They Are Based on the False Assumption That the Science Panel Made a Determination That C-8 Was a Scientific “Cause” of Kidney Cancer.

Dr. Margulis gave unwarranted weight to C-8 in his differential etiology because he falsely assumed that the Science Panel made a scientific determination that C-8 was a “cause” of kidney

cancer. Margulis Report at 2, 6 (*Swartz* ECF No. 27-1); Margulis Depo. at 47:21-48:4. But the Science Panel did not make any such determination; instead, the Science Panel’s ‘probable link’ findings were based on a much lower standard of proof than a finding of causation.⁵

This distinction is critical here, because the false assumption that the Science Panel determined that C-8 was a scientific “cause” of kidney cancer was the foundation on which Dr. Margulis built his *specific* causation opinion in this case. Specifically, Dr. Margulis claims to have summarily ruled out obesity and high blood pressure, two other well-accepted risk factors for Plaintiff’s kidney cancer, from his purported differential etiology because he claimed that these risk factors are merely associated with C-8, not scientifically proven “causes” of kidney cancer like he assumed C-8 was. *See* Margulis Report at 6; Margulis Depo. at 12:19-13:5; 15:16-17:12; 18:10-15; 19:19-20:8; 47:21-48:4.

The Science Panel, after seven years of study, and using the lower standard of proof for a probable link finding for a medical monitoring claim, found a Probable Link between C-8 and kidney cancer, but went no further. The Probable Link Finding regarding cancer was *not* a scientific determination that C-8 actually “causes” cancer, or specifically “caused” cancer in Mrs. Swartz—and Class Members promised that DuPont expressly preserved its ability to contest specific causation. Dr. Margulis’s conclusions improperly conflates the Science Panel’s finding, and improperly skips over every analytical step required to properly opine that C-8 specifically caused Mrs. Swartz’s kidney cancer. Instead, Dr. Margulis assumes without any legitimate scientific basis that a Probable Link Finding was a determinative finding of specific causation.

⁵ As DuPont explains in its contemporaneously filed Motion For Interpretation Of The *Leach* Agreement With Respect To Specific Causation in the *Swartz* Case, incorporated in relevant part here, the parties agreed that the Science Panel’s determinations could be made using the lesser standard of “probable link” that the West Virginia Supreme Court developed for medical monitoring claims in the *Bower* case, rather than the much higher standard of general causation, because the main relief sought in *Leach* was medical monitoring.

In short, Dr. Margulis's opinion that C-8 was more likely than obesity and high blood pressure to be the cause of Plaintiff's kidney cancer is unreliable at its very core, because it is based on a false scientific assumption, and the opinion should therefore be excluded. *See, e.g., Paz v. Brush Engineered Materials Inc.*, 555 F.3d 383 (5th Cir. 2009) (lower court properly excluded testimony of causation expert that based testimony on a "false assumption" and "erroneous information"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 30355 (D.S.C. Feb. 29, 2016) (excluding expert testimony, and stating: "Allowing testimony based on an obviously false assumption, as conceded by Plaintiffs' clinical expert, would be abdicating this Court's role as a gatekeeper under *Daubert*.").

Here, Dr. Margulis compounded this error because he subjectively and unreliably employed two different methodologies: one methodology for C-8, and a different methodology for ruling out all alternative explanations of Plaintiff's kidney cancer. Specifically, Dr. Margulis claimed that he was able to rule out obesity and high blood pressure from his differential analysis because he was not aware of any "conclusive evidence of [a] direct mechanism of action" by which obesity or high blood pressure can cause kidney cancer. Margulis Depo. at 17:3-12.

However, while Dr. Margulis placed determinative weight on his view that there has been no scientific proof of the mechanism of action for how obesity and how high blood pressure cause kidney cancer, Dr. Margulis conceded at his deposition that he also did **not** know of any scientific proof of the mechanism of action by which C-8 causes kidney cancer. *See* Margulis Depo. at 31:3-20.

Dr. Margulis should not be permitted to use a results-oriented, invalid, subjective, and self-serving methodology, invented for litigation, which summarily rules out obesity, high blood pressure, smoking and all other risk factors for kidney cancer, while ignoring that the exact same

methodology he uses to rule out all other risk factors would require him to rule out C-8. Tellingly, Dr. Margulis admitted that he is not aware of any peer-reviewed paper (or even a non-peer reviewed paper) that says you should exclude obesity or high blood pressure from a specific causation analysis for a patient with kidney cancer. *See* Margulis Depo. at 17:15 – 18:9.

In short, Dr. Margulis used an unreliable, subjective and made solely for this litigation methodology of reaching an expert opinion on specific causation, and Dr. Margulis's opinions based on this unreliable and scientifically dishonest approach should be excluded. *See Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F. Supp. 2d 434, 560-61 (W.D. Pa. 2003) (noting unreliability of experts who demand multiple solid epidemiology studies before they will agree to place certain other plausible causes of plaintiff's stroke on the differential etiology, but abandon that standard when it comes to defendant's product); *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.") (internal quote marks omitted); *Barber v. United Airlines, Inc.*, 17 Fed. Appx. 433, 437 (7th Cir. 2001) (finding expert opinion unreliable where expert "ignored certain facts and data, while accepting others")

III. Dr. Margulis's Methodology is Also Unreliable Because He Adopted a "No Safe Dose" Theory and Failed To Account For Plaintiff's Specific Level of Exposure to C-8.

Dr. Margulis's specific causation opinions also are fundamentally unreliable because they take absolutely no account of the Plaintiff's individual's level of exposure to C-8. Dr. Margulis expressly conceded this fundamental error when he admitted at his deposition that *his specific causation opinions would not have changed in any way even if he had assumed that Plaintiff "had only been exposed to one molecule of C-8."* Margulis Depo. at 27:3-7 (emphasis supplied).

Dr. Margulis's specific causation opinions are based on the "no safe dose" theory, which has been resoundingly rejected by other courts as an unreliable specific causation methodology, and the Court should do the same here. *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671 (6th Cir. 2011) (affirming exclusion of specific causation expert partly because "he relied upon a 'no safe dose' theory that had been discredited by other courts as a basis for establishing specific causation"); *Stallings v. Ga. Pacific Corp.*, 675 F. App'x 548 (6th Cir. 2017) (rejecting "any" or "every exposure" theory of causation); *Adams v. Cooper Indus.*, 2007 U.S. Dist. LEXIS 55131 (E.D. Ky. July 30, 2007) ("The court finds that the 'no-safe-dose' theory is not a reliable methodology, and it rejects the plaintiffs' claim that said theory entitled their specific causation experts to pay so little attention to the level of exposure in the bellwether plaintiffs.").

Dr. Margulis admitted that he did nothing to evaluate the amount of Plaintiff's risk of developing kidney cancer based on her exposure to C-8. Margulis Depo at 26:11-26:20; 29:10-20. Without this plaintiff-specific risk information, Dr. Margulis's primary specific causation opinion is fundamentally unreliable because he did not do the required "weighing of risks" between Plaintiff's C-8 exposure and other alternative explanations, including Plaintiff's decades of obesity and high blood pressure. Margulis Depo. at 10:7-11; 13:15-14:3; 26:22-27:1. *See, e.g., Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 610 (D.N.J. 2002) ("In order to properly assess the specific cause of an individual's illness, a quantitative risk assessment must be undertaken, which assesses the risk that a particular exposure caused a particular illness. When an individual is exposed to two or more risk factors, the same method for both risk factors would have to be applied in order to assess the risk attributable to each of those risk factors.")⁶

⁶ *See also* Stout et al., *Bayes' Law, Sequential Uncertainties, And Evidence Of Causation In Toxic Tort Cases*, 38 U. Mich. J.L. Reform 781, 784 (2005) ("the causation expert must conduct a quantitative causation analysis (sometimes called risk analysis) to establish that the agent at issue is the most likely cause of the disease or injury (specific causation). To conduct a valid causation analysis, the expert must

IV. Dr. Margulis's Methodology Is Also Unreliable Because He Did Not Follow the Professional Practices That He Uses Outside the Courtroom.

Dr. Margulis conceded that, in his regular professional practice of medicine outside the courtroom, he tells patients the various risk factors that contribute to kidney cancer, but does *not* tell them that one thing was the cause or a substantial contributing cause of their kidney cancer. *See* Margulis Depo. at 52:1-9.⁷ In his regular professional practice outside the courtroom, he also does not use the unique, artificial and unsupported methodology (discussed above) that he used for his work in this case.

For this additional reason, that the made for litigation approach he used here differs from the approach he has used in his regular professional practice outside the courtroom for the past 10 years, his opinions on specific causation should be excluded. *United States EEOC v. Rockwell Int'l Corp.*, 60 F. Supp. 2d 791, 797 (N.D. Ill. 1999) (excluding expert testimony where the expert “failed to employ the same level of intellectual rigor that characterizes the practice of experts in his field, or even his own normal practice.”); *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 639 (S.D. Tex. 2005) (excluding expert testimony where “the gulf between” the methodology used in the litigation and the methodology the expert advocated for in his academic work “starkly contravene[d]” the requirements of *Daubert*).

CONCLUSION

For each of these reasons, and in the interests of justice, DuPont respectfully requests that the Court preclude Dr. Margulis from offering any specific causation opinions at trial.

apply relevant medical, toxicological, and epidemiologic principles to the facts of the case, weighing alternative potential causes of the injury to identify the most likely cause.”).

⁷ The only exception to this is if he is treating a patient with a known hereditary gene issue. Margulis Depo. at 52:1-9.

Respectfully submitted,

s/ *Damond R. Mace*

Damond R. Mace (0017102) (Trial Attorney)

Aneca E. Lasley (0072366)

Nathan A. Leber (0090770)

Jesse L. Taylor (0088209)

SQUIRE PATTON BOGGS (US) LLP

4900 Key Tower

127 Public Square

Cleveland, Ohio 44114

(216) 479-8500 (Phone)

(216) 479-8780 (Fax)

Attorneys for Defendant E. I. du Pont de Nemours and
Company

CERTIFICATE OF SERVICE

A true and correct copy of the foregoing was electronically filed with this Court's CM/ECF system on this 9th day of July, 2019 and accordingly served automatically upon all counsel of record for this matter.

s/ Damond R. Mace

Damond R. Mace (0017102)

Attorney for Defendant